

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Rudnick et al.

Examiner: D. Isabella

Serial No.: 09/271,304

Group Art Unit: 3738

Filed: March 17, 1999

Docket: 498-67 CON 2

For: NESTED STENT

Dated: May 16, 2000

Date \_\_\_\_\_ Label No. \_\_\_\_\_  
I hereby certify that on the date indicated above I  
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and that it was addressed for delivery to the Assistant  
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Name (Print)\_\_\_\_\_  
(Signature)

Assistant Commissioner for Patents  
Washington, DC 20231

DECLARATION OF PRIOR INVENTION IN  
THE UNITED STATES TO OVERCOME A PATENT UNDER 37 C.F.R. § 1.131

Sir:

1. We, James J. Rudnick, and Dominik M. Wiktor, both citizens of the United States, residing respectively at 11 Clearwater Court, Mahwah, NJ 07430 and 6441 3<sup>rd</sup> Palm Point, Saint Petersburg, Florida 33706-2123, are joint inventors of the above-identified application.
2. At the time of the invention thereof we were working for Meadox Medicals, Inc., assignee of the present application. With respect to the inventor Rudnick, I was an employee of Meadox Medicals, Inc. and with respect to inventor Wiktor, I was a consult

for Meadox Medicals, Inc. We submit this declaration to establish completion of the invention set forth in this application in the United States at a date prior to April 1, 1994, i.e. the effective date of U.S. Patent No. 5,876,432, Lau et al. (hereinafter the '432 patent), which was cited by the Examiner in an Office Action mailed December 29, 1999.

3. From the documents submitted herewith and as set forth hereinbelow, it can be seen that the invention was completed in the United States before April 1, 1994 which is a date earlier than the U.S. filing date of the '432 patent. Completion of the invention prior to April 1, 1994, is shown by conception and actual reduction to practice of the invention as evidenced by construction and testing of a nested stent.
4. To establish conception and reduction to practice, i.e. completion of the invention at a date prior to April 1, 1994, the following documents being submitted as evidence:
  - a. A Meadox Medicals, Inc. invention disclosure (Exhibit A) bearing dates signed by the inventors and dates signed by witnesses prior to April 1, 1994, the filing date of the '432 patent. (The dates have been redacted to prevent their unnecessary disclosure.) That invention disclosure describes the nested stent of the present invention where the benefits of the device are described as follows: "all of the above being accomplished by providing maximum monofilament wire density in a minimum volume of space by proper nesting of convolutions of formed wire over a mandrel." In an attachment to that invention disclosure, a drawing of the nested

stent is shown. The drawing shown in the attachment to the invention disclosure is substantially similar to the drawings shown in Figures 2 and 8 of the present application. This invention disclosure evidences conception of the invention prior to April 1, 1994.

- b. A confidential report entitled "Stent Analysis Summary" (Exhibit B) prepared by Product Genesis Inc., an engineering and design firm, which was retained by assignee, Meadox Medicals, Inc., to conduct an engineering analysis of the nested stent which is the subject of the claims of the present application. That report bearing a final issue date prior to April 1, 1994 (also redacted), includes a drawing labeled Figure 2-2 "Stacked Packing Geometry" showing a drawing of the nested stent of the present invention. Further and as evidence of completion of the invention, the report of Exhibit B includes photographs at Figures 4-4 through 4-7 showing the constructed nested stent of the present invention. Also as an attachment to this report are two spreadsheets showing design variables for construction of the nested stent of the present invention. Certain of these design variables have been included in the present application, being incorporated into Table 1.

- 5. The materials submitted herewith establish that the invention was completed, i.e. conceived and reduced to practice at a date prior to April 1, 1994, the filing date of the '432 patent.

6. This declaration is submitted in a response to a first Office Action issued by the Examiner and is therefore believed to be timely filed.
7. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATED: MAY 17, 2000

  
James J. Rudnick

DATED: \_\_\_\_\_

\_\_\_\_\_  
Dominik Wiktor



1. GIVE TITLE OF YOUR IDEA:

## HI-STRENGTH HI-WIRE DENSITY INTRAVASCULAR EXPANDABLE STENT

2. DESCRIBE YOUR IDEA IN DETAIL AND INCLUDE SKETCH AND FORMULA IF NECESSARY:

Intraluminal Stent characterized by its ability to resist external compressive forces, also to discourage encroachment of cell ingrowth between wires after deployment, yet maintain full flexibility; all of the above being accomplished by providing maximum monofilament wire density in a minimum volume and space. by proper nesting of convolutions of formed wire over a mandrel

3. STATE ADVANTAGES OVER EXISTING PRODUCTS OR METHODS:

Presently used and known Stents, specifically as shown in US Pat 4,886,062 by Wiktor, although similar in design and basic construction do not provide high strength nor tight wire nesting as the Stent of this Invention.

4. ATTACH AND IDENTIFY COPIES OF ALL KNOWN REFERENCES, DRAWINGS, SKETCHES, DESCRIPTIONS, DATA, ARTICLES, TEXTBOOKS, ETC. (Note: All entries made in Laboratory Notebooks, memoranda, correspondence or similar documentation by author, recipient, date, project number, book number, and page number, if applicable. Concept Meeting,

First memo to J. Rudnick, subsequent meeting at MEADOX Dominik M. Wiktor developed thus reduced a theoretical idea to a a working model; several models constructed and expanded over a balloon, additional samples constructed and together with a memo sent to MEADOX

5. GIVE NAMES OF OTHER PERSONS FAMILIAR WITH OR WHO HAVE WORKED ON PROJECT:

Dominik M. Wiktor  
James J. Rudnick

Brent Nixon

SIGNATURE(S) OF INVENTOR(S)	DATE	PRINT NAME OF INVENTOR(S)	HOME ADDRESS
<i>Dominik M. Wiktor</i>		Dominik M. Wiktor	4 Culin Drive Cranford, NJ 07016
<i>James J. Rudnick</i>		James Rudnick	74 Moore Ave, Waldwick, NJ 07463

WITNESSED AND UNDERSTOOD BY:

*Anthony M. Spadaro* Signature

Anthony M. Spadaro Print Name

Date: \_\_\_\_\_

APPROVED FOR FURTHER PATENT REVIEW:

☐ Yes ☐ No \_\_\_\_\_ Date: \_\_\_\_\_

☐ Yes ☐ No \_\_\_\_\_ Vice President Date: \_\_\_\_\_

EXECUTIVE COMMITTEE REVIEW:

☐ Approved for Patentability Opinion \_\_\_\_\_ President Date: \_\_\_\_\_

☒ Approved for Patent Application *[Signature]* \_\_\_\_\_ President Date: \_\_\_\_\_

☐ Other (explain below) \_\_\_\_\_ President Date: \_\_\_\_\_

Comments: \_\_\_\_\_

BOOK NO.:

PAGE NO.: 1 of 1

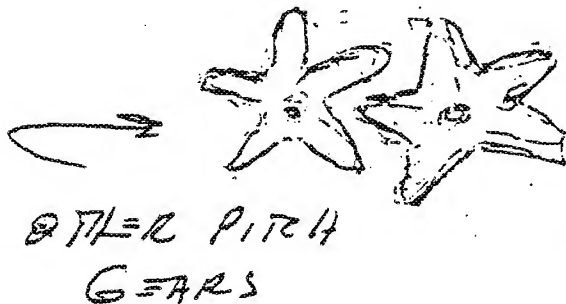
PROJECT NO.:

DATE:

SUBJECT:

H1 STRENGTH - H1 WIRE DENSITY  
INTRAVASCULAR EXPANDABLE STENT

1. TANTALUM WIRE PREFORMED OVER GEARS



James J. Rudnick  
JAMES J. RUDNICK

by  
RECORDED

Dominik M. Viktor

INVENTOR

DATE

DOMINIK M. VIKTOR

WITNESS

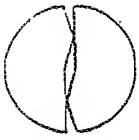
DATE

Anthony M. Spindler

EACH PAGE MUST BE SIGNED, WITNESSED, AND DATED.







Product Genesis Inc.

Engineering Design and Product Development

300 Bent Street  
Suite 200  
Cambridge, MA 02141  
617 661 3552  
FAX 617 661 0126

## Stent Analysis Summary

FINAL ISSUE

For:  
Meadox/SurgiMed  
112 Bauer Drive  
Oakland, NJ 07436  
1-800-221-1542

By:  
Product Genesis, Inc.  
300 Bent Street, Suite 200  
Cambridge, MA 02141  
617-661-3552

**CONFIDENTIAL**

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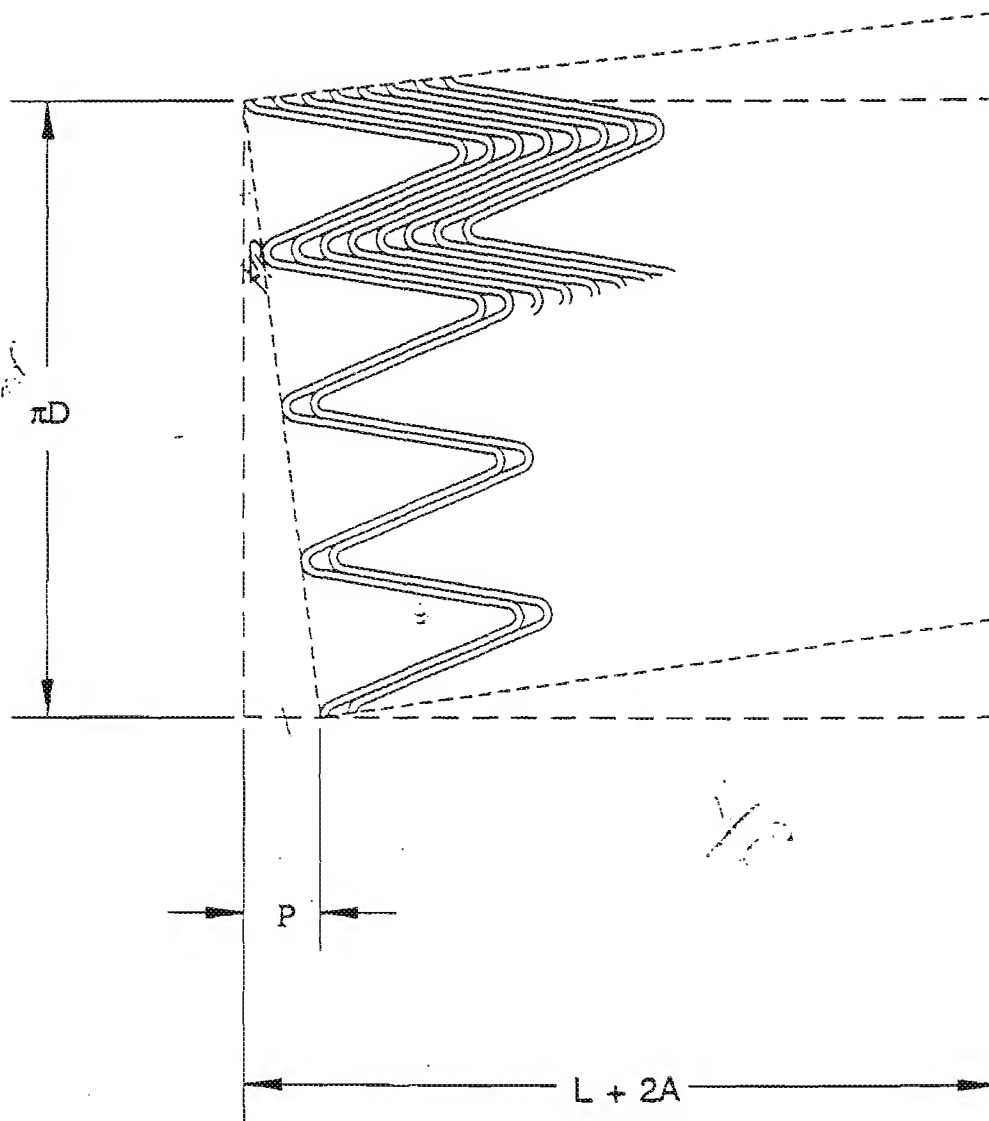
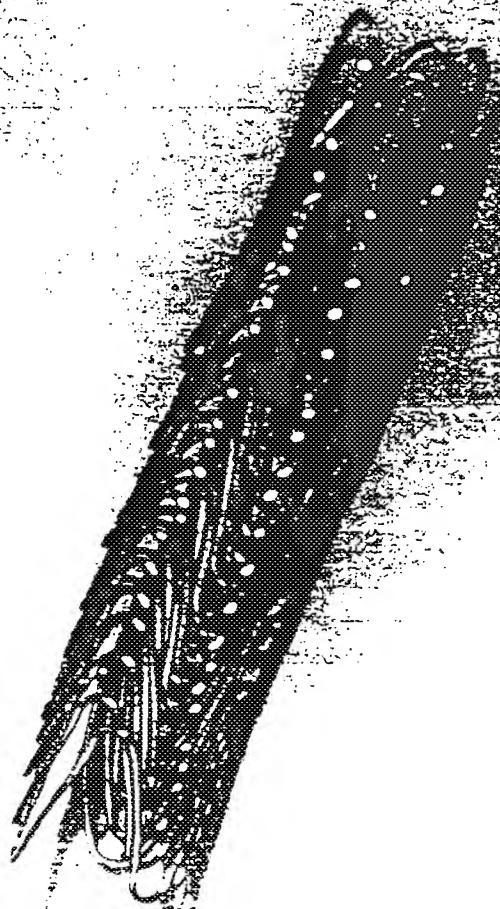
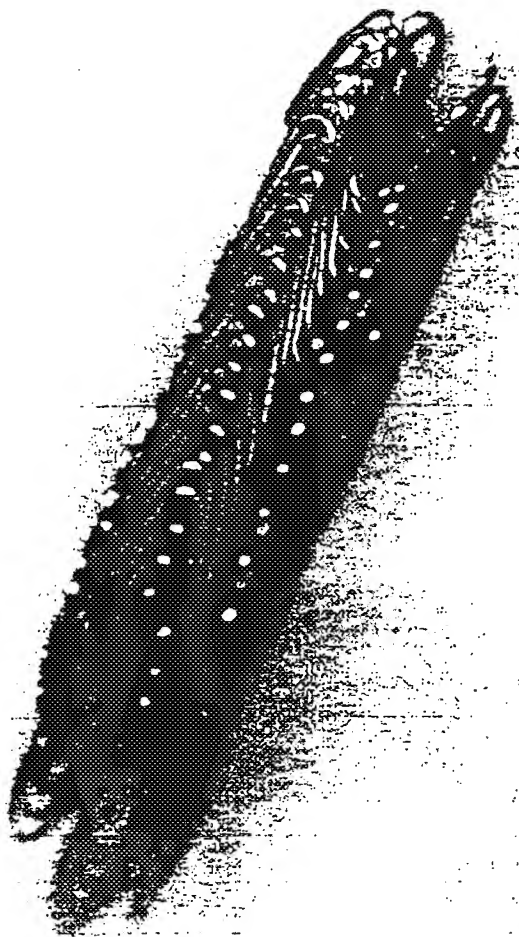


Figure 2-2: Stacked Packing Geometry



1000  
900  
800  
700  
600  
500  
400  
300  
200  
100

Figure 1-5

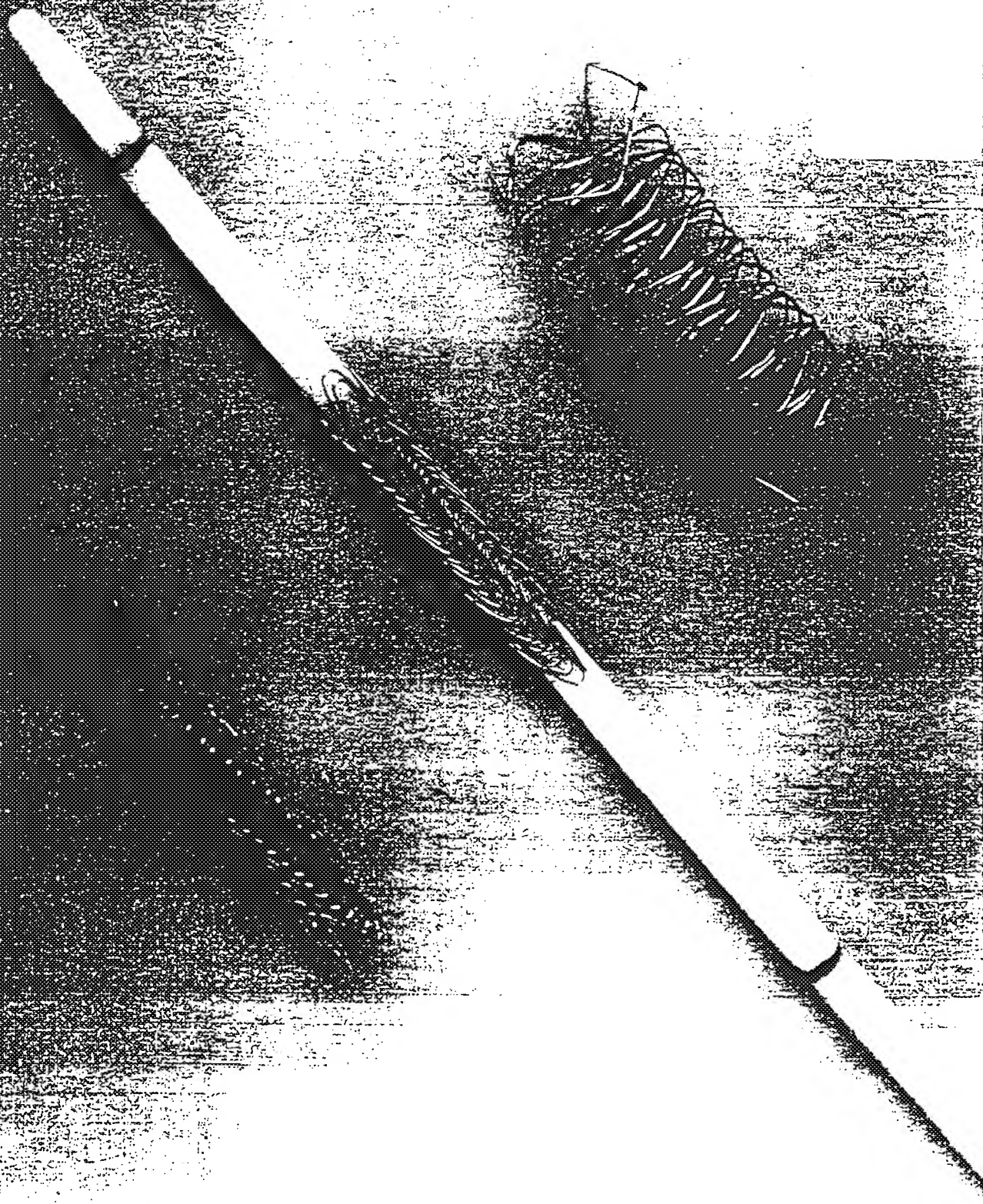


Figure 1.6



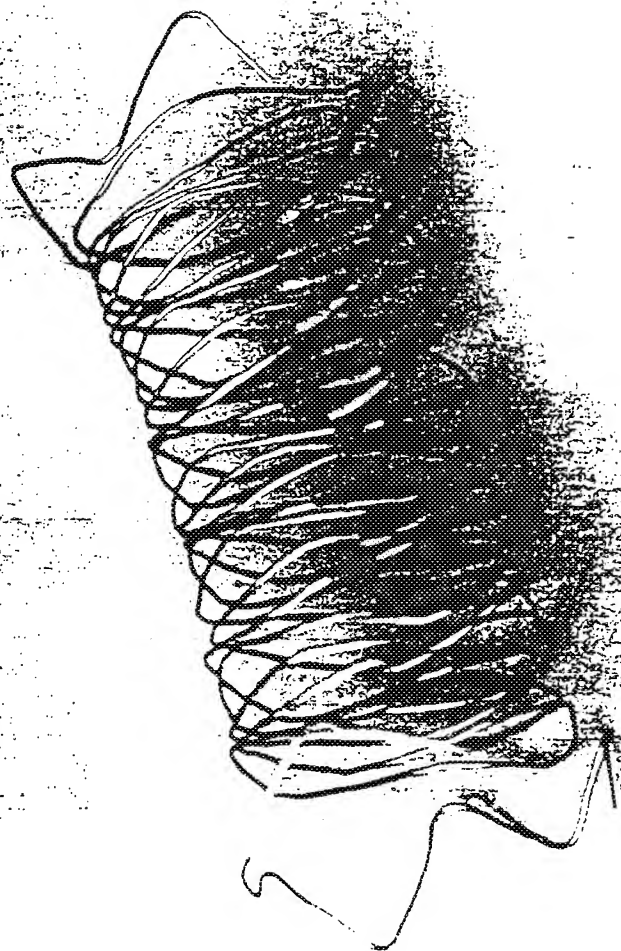


Figure 1-2

CONFIDENTIAL									
Measos									
Stack Packed Slent Geometry									
Design Variables:									
1	L (")	1.000							
2	D (") closed	0.157							
3	D (") open	0.472							
4	A <sub>1</sub> (psi)	10.000							
5	d (")	0.010							
6	r (") closed	0.020							
7	N	3							
8	M	22.47							
Outputs:									
[Eq #]									
S1	λ (") closed	0.165	>	0.117	S36				
4	A <sub>1</sub> (") closed	0.114	<	90	8				
9	θ (") open	85.0							
S2	θ (") closed	13.0							
1	λ (") open	0.485							
6	A <sub>1</sub> (") open	0.010	>	0	28				
3	r (")	0.097	>	0	31				
10	Lw (")	35.147							
	Wire Area	0.351							
11	% lost	28.958							
21	T (lb)	0.105							
22	1 (") 4	4.609E-10							
12	P <sub>0</sub>	4.223E-01							
26	N	1.02							
27	K <sub>0</sub>	0.98							
Point A									
17	V <sub>x</sub> (lb)	0.000							
17	V <sub>y</sub> (lb)	0.041							
18	M <sub>x</sub> (lb)	3.53E-04							
18	M <sub>y</sub> (lb)	5.08E-04							
22	σ (psi)	5783.							
23	ε (psi)	1800.							
28	ε (psi)	8795.	<	67.000	Tresca				
Point B									
19	V <sub>x</sub> (lb)	0.105							
19	V <sub>y</sub> (lb)	0.041							
20	M <sub>x</sub> (lb)	0.00E+00							
20	M <sub>y</sub> (lb)	1.01E-03							
22	σ (psi)	11000.							
23	ε (psi)	1785.							
28	ε (psi)	11584.	<	67.000	Tresca				
Stress Concentration Variables									
	R/c	47.244							
	r/c	0.003							
Trigonometric Variables									
	cos(theta cl)	0.974							
	sin(theta cl)	0.225							
	cos(theta op)	0.087							
	sin(theta op)	0.998							
Load Areas and Centroids									
	Area1	0.00088787							
	Area2	2.1814E-05							
	Area3	0.00098787							
Equation #:									
	x1	0.00421841							
	x2	0.010							
	x3	0.00421841							
Equation #:									
	x1	0.00421841							
	x2	0.010							
	x3	0.00421841							
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	x1	0.00421841							
	x2	0.010							
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Equation #:									
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	x3	0.00421841							







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Name (Print)

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DATED: \_\_\_\_\_

James J. Rudnick

DATED: MAY 18 2000

  
\_\_\_\_\_

Dominik Wiktor



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HI-STRENGTH HI-WIRE DENSITY INTRAVASCULAR EXPANDABLE STENT

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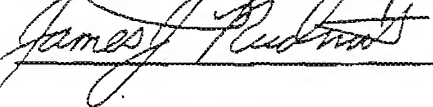
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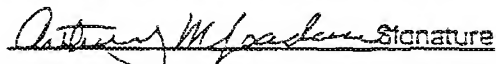
## 5. GIVE NAMES OF OTHER PERSONS FAMILIAR WITH OR WHO HAVE WORKED ON PROJECT:

Dominik M. Wiktor  
James J. Rudnick

Brent Nixon

SIGNATURE(S) OF INVENTOR(S)	DATE	PRINT NAME OF INVENTOR(S)	HOME ADDRESS
		Dominik M. Wiktor	4 Culin Drive Cranford, NJ 070
		James Rudnick	74 Moore Ave, Waldwick, NJ 07463

## WITNESSED AND UNDERSTOOD BY:



Anthony M. Spadaro Print Name

Date: \_\_\_\_\_

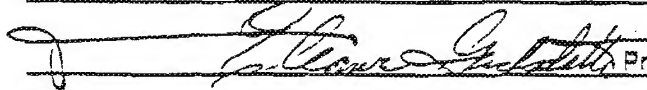
## APPROVED FOR FURTHER PATENT REVIEW:

☐ Yes ☐ No \_\_\_\_\_ Date: \_\_\_\_\_

☐ Yes ☐ No \_\_\_\_\_ Vice President Date: \_\_\_\_\_

## EXECUTIVE COMMITTEE REVIEW:

☐ Approved for Patentability Opinion \_\_\_\_\_ President Date: \_\_\_\_\_

☒ Approved for Patent Application  \_\_\_\_\_ President Date: \_\_\_\_\_

☐ Other (explain below) \_\_\_\_\_ President Date: \_\_\_\_\_

Comments: \_\_\_\_\_

BOOK NO.:

PAGE NO.: 1 of 1

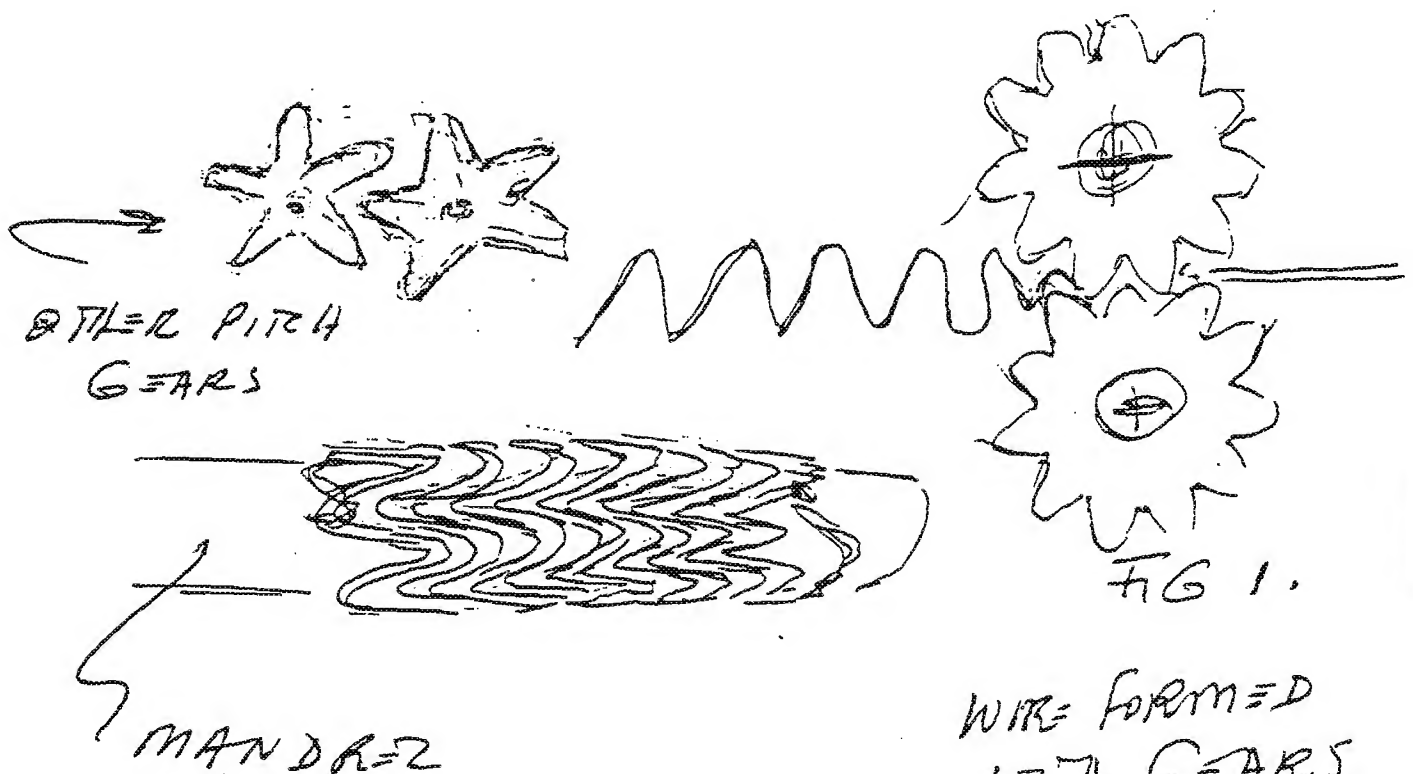
PROJECT NO.:

DATE:

SUBJECT:

H1 STRENGTH - H1 WIRE DENSITY  
INTRAVASCULAR EXPANDABLE STENT

1. TANTALUM WIRE PRE-FORMED OVER GEARS



James J. Rudnick  
JAMES J. RUDNICK

by  
RECORDED

Dominik M. Viktor  
INVENTOR  
DOMINIK M. VIKTOR

DATE

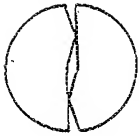
Anthony M. Spidner  
WITNESS

DATE



ALL INFORMATION CONTAINED HEREIN IS UNCLASSIFIED  
DATE 06/22/00 BY 60322 UCBAW





Product Genesis Inc.

Engineering Design and Product Development

300 Bent Street  
Suite 200  
Cambridge, MA 02141  
617 661 3552  
FAX 617 661 0126

## Stent Analysis Summary

FINAL ISSUE

For:  
Meadox/SurgiMed  
112 Bauer Drive  
Oakland, NJ 07436  
1-800-221-1542

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Cambridge, MA 02141  
617-661-3552

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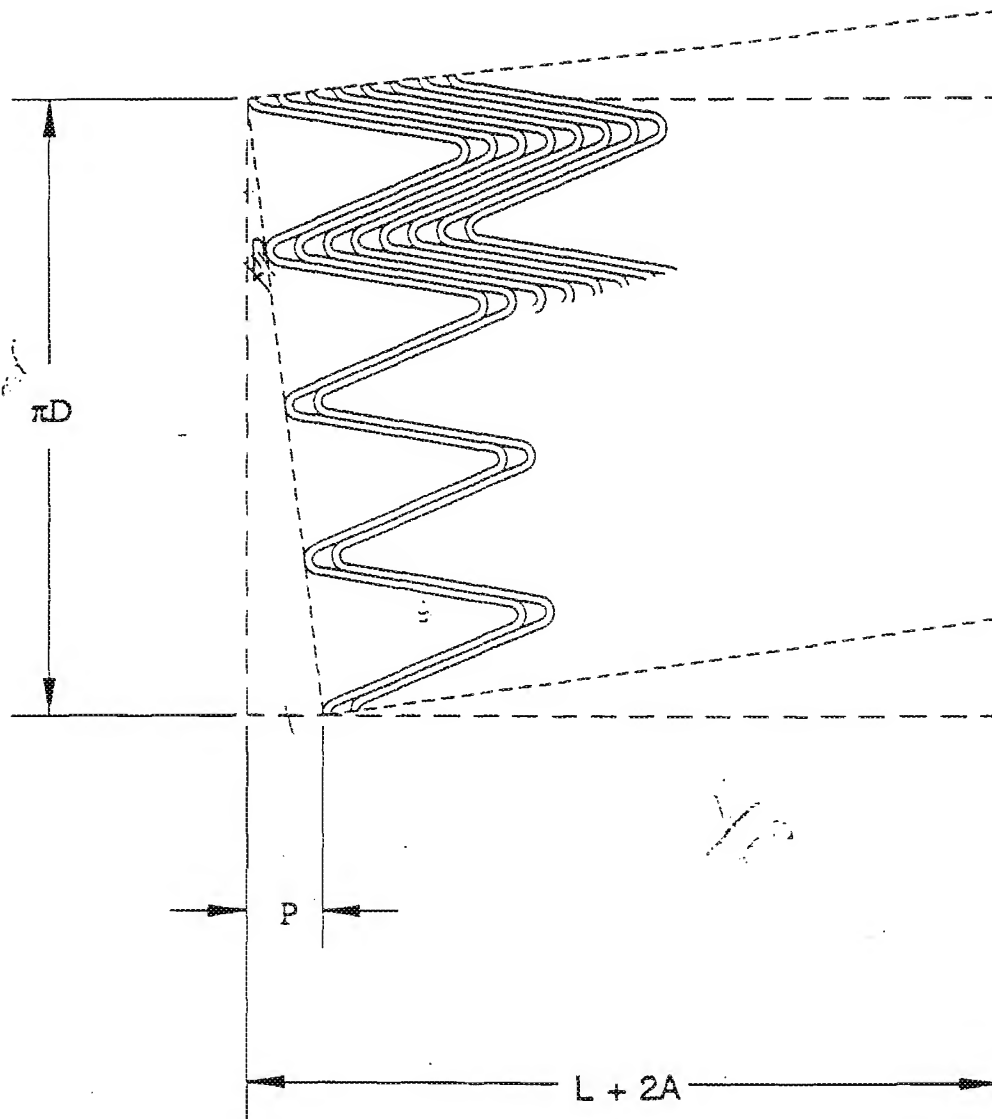
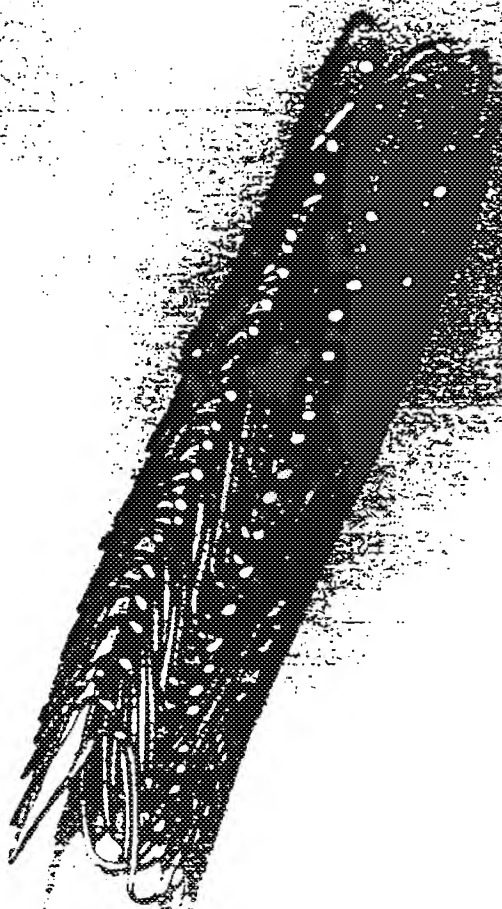
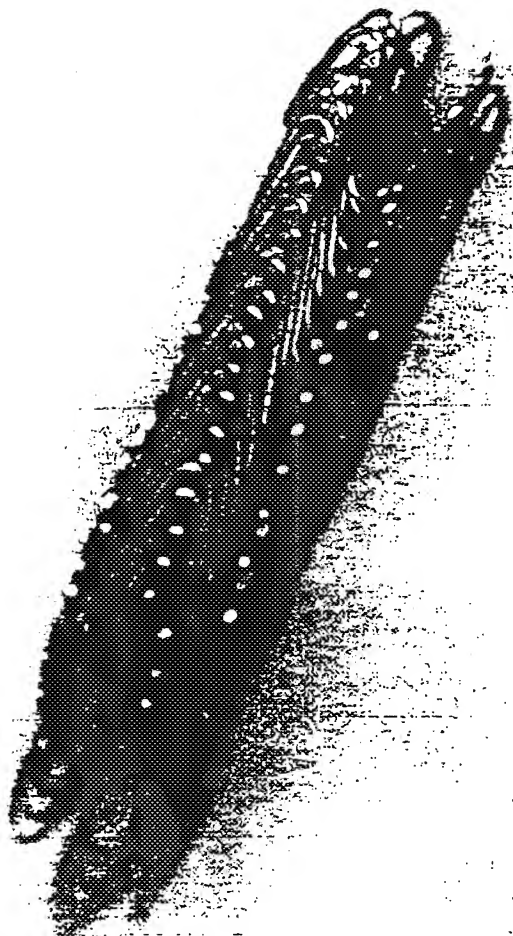


Figure 2-2: Stacked Packing Geometry



11-21001

Figure 4-5

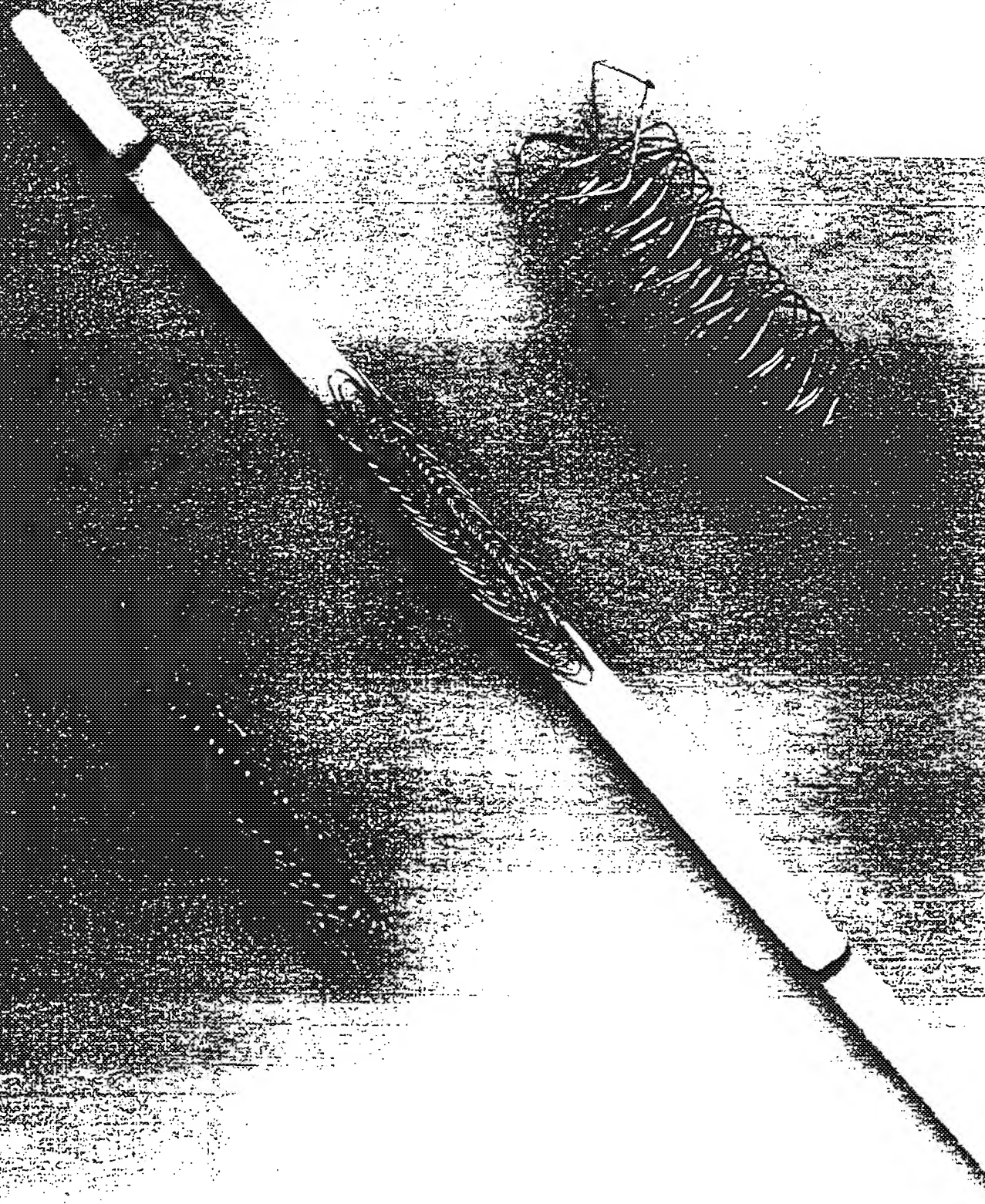


Figure 4.6



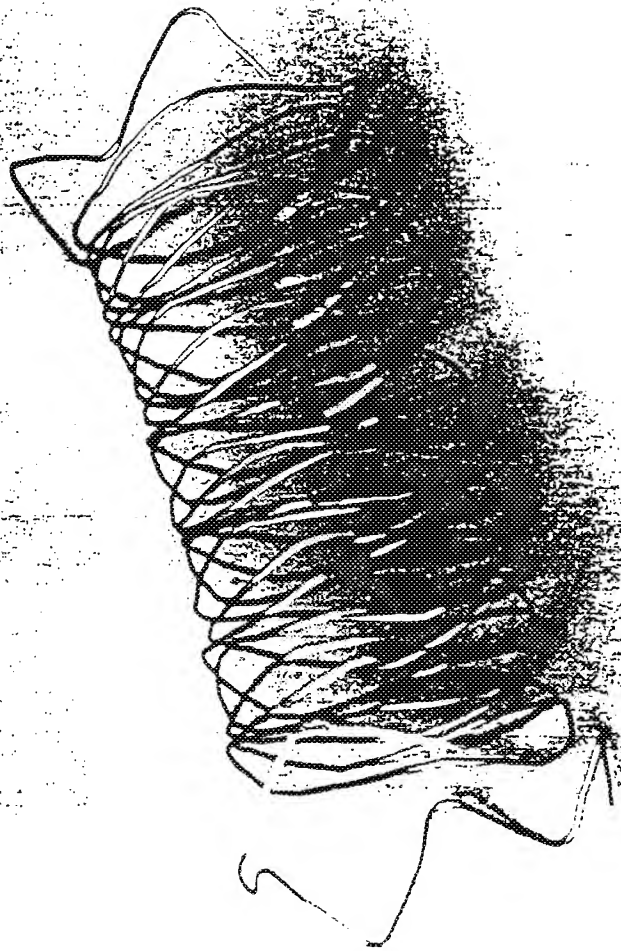


Figure 1-2

CONFIDENTIAL

CONFIDENTIAL											
Meadow Slack Packed Sient Geometry											
Design Variables:											
1	L (")	1.000									
2	D (") closed	0.157									
3	D (") open	0.472									
4	PJ (psi)	10.000									
5	d (")	0.010									
6	r (") closed	0.020									
7	N	3									
8	M	22.47									
Outputs:											
(Eq #)											
S1	λ (") closed	0.165									
4	A (") closed	0.114									
9	θ (") open	85.0									
S2	θ (") closed	13.0									
1	λ (") open	0.495									
8	A (") open	0.010									
3	r (")	0.097									
10	Lw (")	35.147									
Wire area		0.351									
11	% lost	28.958									
21	T (lb)	0.105									
22	T (")^4	4.908E-10									
12	Ps	4.223E+01									
26	h	1.02									
27	h/c	0.98									
Point A											
17	Vx (lb)	0.000									
17	Vz (lb)	0.041									
18	My (lb)	3.53E-04									
18	Mz (lb)	5.06E-04									
22	σ (psi)	5783.									
23	ε (psi)	1800.									
28	e (psi)	8795.									
Point B											
19	Vx (lb)	0.105									
19	Vz (lb)	0.041									
20	My (lb)	0.00E+00									
20	Mz (lb)	1.01E-03									
22	σ (psi)	11000.									
23	ε (psi)	1785.									
28	e (psi)	11584.									
Constraints:											
(Eq #)											
>	0.117	S38									
<	80	8									
>	0	29									
>	0	31									
Stress Concentration Variables											
R/c		47.244									
h/c		0.005									
Trigonometric Variables											
cos(theta cl)		0.974									
sin(theta cl)		0.225									
cos(theta op)		0.087									
sin(theta op)		0.996									
Load Areas and Centroids											
Area1		0.00098787									
Area2		2.1814E-05									
Area3		0.00098787									
Equation #:		13									
x1		0.00421641									
x2		0.010									
x3		0.00421641									
Equation #:		14									
x1		0.00421641									
x2		0.010									
x3		0.00421641									
Equation #:		14									
x1		0.00421641									
x2		0.010									
x3		0.00421641									
Equation #:		14									
x1		0.00421641									
x2		0.010									
x3		0.00421641									
Equation #:		14									
x1		0.00421641									
x2		0.010									
x3		0.00421641									
Equation #:		14									
x1		0.00421641									
x2		0.010									
x3		0.00421641									
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x2		0.010									
x3		0.00421641									
Equation #:		14									
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